Application No.: 10/551,977

Ø1013/045

NOV 1 3 2006 Docket No.: KZI-002US

REMARKS

Claims 1, 4-10, 12-17, 21, 23-38, and 41-49 were pending in this application. Claims 6 and 12 have been amended to correct typographical errors. Therefore, claims 1, 4-10, 12-17, 21, 23-38, and 41-49 will be pending upon entry of the instant amendment. No new matter has been added.

Cancellation of and/or amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of and/or amendments to the claims are being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application. The amendments made to the claims are not related to any issues of patentability.

Response to Restriction Requirement

The Examiner has required restriction between the following inventions in the aboveidentified application:

Group I, claims 1, 4-10, 12, 17, 28-30, 41-47, and 49, drawn to a recombinant fusion peptabody, which binds epidermal growth factor receptor;

Group II, claims 13-16, and 48, drawn to a nucleic acid, vector, and host cell;

Group III, claim 21, drawn to a method of treating or preventing cancer;

Group IV, claims 23 and 24, drawn to a method of inducing apoptosis;

Group V, claims 25-26, drawn to a method of inhibiting cell proliferation;

Group VI, claim 27, drawn to a method of diagnosing cancer; and

Group VII, claims 31-38, drawn to a method of producing a fusion peptabody.

In response, Applicants hereby elect Group I, Claims 1, 4-10, 12, 17, 28-30, 41-47, and 49, with traverse. Applicants' election of the foregoing subject matter is without prejudice to Applicants' rights to pursue non-elected subject matter in other applications.

Applicants respectfully traverse the Restriction Requirement as a whole on the ground that the requirement conflicts with the finding of lack of unity during the international stage of the instant application. Specifically, Applicants note that during the international phase of International Application No. PCT/IB2004/001049, of which the present case is a 35 U.S.C. §371 national phase application, the International Searching Authority found the following groups of invention:

- 1. Claims 1-44 (all partially); a fusion peptabody having features (a), (b), and (c) of claim 1 wherein the EGFR ligand is as defined in claim 10(a). DNA encoding said peptabody, vector, cells, uses, methods, and kits comprising said peptabody.
- 2. Claims 1-44 (all partially); as subject 1 wherein the EGFR ligand is as defined in claim 10(b).
- 3. Claims 1-44 (all partially); as subject I wherein the EGFR ligand is as defined in claim 10(c).
- 4. Claims 1-44 (all partially); as subject 1 wherein the EGFR ligand is as defined in claim 10(d).
- 5. Claims 1-44 (all partially); as subject 1 wherein the EGFR ligand is as defined in claim 10(e).
- 6. Claims 1-44 (all partially); as subject 1 wherein the EGFR ligand is as defined in claim 10(f).
- 7. Claims 1-44 (all partially); as subject 1 wherein the EGFR ligand is as defined in claim 10(g).

8. Claims 1-44 (all partially); as subject 1 wherein the EGFR ligand is as defined in claim 10(h).

- 9. Claims 1-44 (all partially); as subject 1 wherein the EGFR ligand is as defined in claim 10(i).
- 10. Claims 1-44 (all partially); as subject 1 wherein the EGFR ligand is as defined in claim 10(j).
 - 11. Claim 45; an enhancer sequence as defined in claim 45.

For the convenience of the Examiner, Applicants enclose herewith a copy of the International Search Report (enclosed herewith as Appendix A) and the Written Opinion (enclosed herewith as Appendix B) which describe the unity of invention decision from the international application. Applicants also submit herewith Appendix C, which contains a listing of the pending claims in the present application and the corresponding claims from the international application.

As discussed in Item IV of the attached Written Opinion (Appendix B), 11 different groups of inventions were recognized during the international stage of the instant application. The common concept found to link groups 1-10 together, was the combination of technical features of the peptabodies of claim 1. The enhancers referred to in claim 45 of the international application (see corresponding claim 41 of the instant application) were grouped separately from the peptabodies of groups 1-10. With regard to the peptabodies of groups 1-10, the International Searching Authority grouped the inventions according to the different ligands referred to in claim 10 (claim 6 of the currently pending U.S. application).

PCT Article 27 provides that it is improper for national offices to require compliance with the requirements relating to the form or contents of the application different from or additional to those which have been provided for in the PCT. Further, MPEP §1850 states that:

...when the Office considers international applications as an International Searching Authority, as an International Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. (emphasis added)

Indeed, the same standard for unity of invention is applicable to both international applications and national phase applications. Accordingly, Applicants submit that the lack of unity of invention in the present case should mirror the lack of unity of invention found in the international stage, *i.e.*, the multiple groups of invention should be the same for both the international stage of the application and the national stage of the application.

For the foregoing reasons, Applicants respectfully request the withdrawal of the present Restriction Requirement. Applicants also respectfully request the issuance of a new Restriction Requirement based on the unity of invention decision made during the international phase of the instant application.

Additionally, Applicants note that during the international stage Applicants elected to pay an additional search fee corresponding to the subject matter of group 11. Thus, inventions 1 and 11 of the international application were previously searched. Applicants submit that in accordance with MPEP §803, if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. In view of the fact that groups 1 and 11 of the international application were previously searched, Applicants submit that it would not place a serious burden on the Examiner to search groups 1 and 11 together.

Additionally, Applicants assert that the traversal of the instant Restriction Requirement is without prejudice to the Applicants' right to traverse a further Restriction Requirement raised in this or a subsequently filed application.

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SUMMARY

NOV 1 3 2006

It is respectfully submitted that this application is in condition for allowance. If there are any remaining issues, or if the Examiner believes that a telephone conversation with Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400. Please charge any additional fees or credit any overpayments to our Deposit Account No. 12-0080, under Order No. KZI-002US from which the undersigned is authorized to draw.

Dated: November 13, 2006

Respectfully submitted,

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